



**FLORIDA SOCIETY OF CLINICAL ONCOLOGY**  
**FLASCO BLAST June 16 2010**  
**FLASCO WEBSITE: [www.flasco.org](http://www.flasco.org)**  
**FLASCO CLINICAL TRIALS NETWORK WEBSITE: [www.fctn.org](http://www.fctn.org)**

**MESSAGE FROM FLASCO PRESIDENT: Gerald Robbins, MD**

FLASCO Executive Director, Dorothy Green Phillips, and I attended the FSGO Annual Meeting in Longboat Key this past weekend. Congratulations to FSGO on a very successful meeting. Our two State Societies are looking at potential ways we can work together in the future.

Members of the FLASCO Ad Hoc Committee on Payer Relations will be meeting with representatives of Aetna, Av Med, Humana, BCBS and UHC on June 25, in Tampa. The objectives of this meeting are:

- To identify the issues – Payers and FLASCO
- To provide an opportunity for the payer community to share their concerns re cost, quality, value, etc.
- To develop and agree on specifics and put into place mechanisms for a more formal structured relationship between FLASCO/Payers
- To present FLASCO strategic plan of action

**DRUG UPDATES:**

**Oforta - New Q code - Q2025 starting July 1, 2010**

Centers for Medicare & Medicaid Services (CMS) has assigned a new HCPCS billing code to OFORTA™ (fludarabine phosphate tablets), effective for dates of service on or after **July 1, 2010: Q2025 (fludarabine phosphate, oral, 1 mg)**

Q2025 (fludarabine phosphate, oral, 1 mg) should replace code J8999 (Prescription drug, oral, chemotherapeutic, not otherwise specified) when submitting Medicare claims for OFORTA™ for dates of services on or after July 1, 2010. Correct billing for OFORTA™ must be billed to reflect a 1 mg billing unit:

**Example: One 10 mg tablet = 10 billing units of Q2025**

**NOTE:** Other payers, including private payers and Medicaid programs, may update their claims processing systems with this new code on an alternate schedule. Many payers will continue to require the NDC, rather than Q2025, when billing for OFORTA™.

**ISTODAX (Romidepsin for injection)**

In the US, ISTODAX is indicated for the following use:

- Treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy.

ISTODAX will be distributed only by specialty distributors, please call Celgene Customer Care at: 888.423.5436 for further details.

**FCSO UPDATES:**

**G0430: Qualitative drug screening -- revision to the LCD**

**LCD ID number: L30574 (Florida/Puerto Rico/U.S. Virgin Islands)**

The local coverage determination (LCD) for qualitative drug screening was most recently revised on April 1, 2010. Since that time, a revision was made to the “Indications” section of the LCD. Under the “Indications” section of the LCD, the statement “For management of chronic pain patients when there is a high pre-test suspicion of non-adherence to the prescribed drug regimen as documented in the patient’s medical record” was deleted. Additionally, the statements

“The management of patients with chronic pain in which there is a significant pre-test probability of non-adherence to the prescribed drug regimen as documented in the patient’s medical record” and “The management of patients with chronic pain in a designated pain management clinic where this select population has a significant pretest probability of drug interactions and side effects” were added under the “Indications” section of the LCD.

#### **Effective date**

This LCD revision is effective for claims processed **on or after June 1, 2010**, for services rendered **on or after January 25, 2010**. First Coast Service Options Inc. LCDs are available through the CMS Medicare Coverage Database at <http://www.cms.gov/mcd/overview.asp>.

Coding Guidelines for an LCD (when present) may be found by selecting “LCD Attachments” in the “Jump to Section...” drop-down menu at the top of the LCD page.

#### **Florida Part B draft local coverage determination (LCD) statuses**

***Modified: 6/9/2010 Location: FL Line of Business: Part B***

Learn the status of local coverage determinations (LCDs) -- for Part B providers in Florida -- as well as information regarding comment periods and final release dates for each LCD

[http://www.cms.gov/mcd/viewlcd.asp?lcd\\_id=30873&lcd\\_version=2&show=all](http://www.cms.gov/mcd/viewlcd.asp?lcd_id=30873&lcd_version=2&show=all)

#### **Ambulatory surgical centers (ASC)**

##### **Revisions to the 2010 ambulatory surgical center payment system**

***Modified: 6/11/2010 Location: FL, PR, USVI Line of Business: Part B***

Medicare contractors have been directed to amend payment files to reflect retroactive changes to the calendar year 2010 hospital outpatient prospective payment system and Medicare physician fee schedule payment rates. [MM7010]

[http://medicare.fcso.com/Data\\_files/162262.pdf](http://medicare.fcso.com/Data_files/162262.pdf)

#### **FDA UPDATES:**

FDA approved hexaminolevulinate hydrochloride (Cysview for Intravesical Solution, Photocure ASA), as an optical imaging agent for use in combination with the Karl Storz Photodynamic Diagnostic D-Light C (PDD) System for cystoscopic detection of non-muscle invasive papillary cancer of the bladder for patients suspected or known to have lesion(s) on the basis of a prior cystoscopy. (May 28, 2010)

More Info: <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm215515.htm>

#### **FDA to post risk summaries of newly approved drugs online**

The FDA announced Tuesday that it will begin posting to its website summaries of the safety risks of recently approved drugs. Gerald Dal Pan, director of the Office of Surveillance and Epidemiology in the FDA's Center for Drug Evaluation and Research, commented that the summaries provide "an early detection mechanism for potentially serious risks and complements the FDA's analysis of safety data during drug development and the agency's routine monitoring of safety information after product approval

#### **UNITED HEALTHCARE UPDATES:**

##### **Intensity Modulated Radiation Therapy (IMRT)**

As of November 1, 2009 UnitedHealthcare required advance notification for all members receiving IMRT services. Advance notification was required for the CPT codes 77301 (Intensity modulated radiotherapy plan), 77418 (intensity modulated treatment delivery, single or multiple fields / arcs, per treatment session) and 0073T (Compensator-based beam modulation treatment delivery).

Over the past months we have evaluated the advance notification requirement and have determined that effective immediately, we will **no longer require advance notification for CPT code 77301 (IMRT treatment plan)**. If UnitedHealthcare receives a request for IMRT services for an unproven condition, we will send the submitted clinical information to a radiation therapist for an expert opinion. We believe the availability of the IMRT treatment summary will provide the radiation therapists with information that has the opportunity to speed the review process.

Additionally, we are not requiring advance notification for CPT code 77338 (multi-leaf collimator device for intensity modulated radiation therapy).

## **IMRT Policy**

The UnitedHealthcare policy states the use of IMRT is proven for the following conditions:

- Primary Bone and Articular Cartilage Cancer of the skull and face, vertebral column, sacrum, and coccyx
- Anal cancer
- Esophageal cancer
- Prostate cancer
- Trachea cancer
- Head and neck cancer
- Malignant (primary and secondary) and benign nervous system neoplasms of the brain (including cranial nerves and cerebral meninges) and spinal cord (including spinal meninges)

Use of IMRT for conditions not listed above would be considered unproven and therefore not a covered health service. However, IMRT may be indicated for an unproven diagnosis when at least one of the following conditions is present:

- The target volume is in close proximity to critical structures that must be protected OR
- An immediately adjacent area has been previously irradiated and abutting portals must be established with high precision

### **Key Points:**

- UnitedHealthcare continues to require advance notification for IMRT services. This includes CPT codes 77418 and 0073T.
- UnitedHealthcare **no longer requires** advance notification for CPT code 77301, Intensity modulated radiotherapy plan
- IMRT services that are not considered proven will be reviewed by a radiation therapist. Clinical information and the IMRT radiotherapy plan are necessary for the review.
- **Cases considered unproven and submitted WITHOUT the IMRT radiotherapy plan may require additional time for review. If the information is not submitted timely, we may not have sufficient information to provide a complete and accurate review.** Submitted
- information needs to support why the case meets one of the above listed conditions where IMRT maybe indicated.
- Requests for IMRT for members insured by UnitedHealthcare should have a completed IMRT notification form faxed to 866-756-9733.
- The UnitedHealthcare IMRT policy is available for your review at *UnitedHealthcareOnline.com > Tools & Resources > Policies & Protocols > Medical Policies*
- **A revised UnitedHealthcare IMRT Data Collection form is available for your use. It can also be found at UnitedHealthcareonline.com > Clinical Resources > Cancer - Oncology > IMRT.**

### **NCCN Reviews for Use of Bevacizumab (Avastin)**

In 2008 UnitedHealthcare and Oxford Health Plans (Oxford) announced the use of the National Comprehensive Cancer Network (NCCN) Compendium for reviewing outpatient chemotherapy drug coverage requests. The UnitedHealthcare Oncology Medication Clinical Coverage policy outlines the use of the NCCN compendium in our decision making process.

The Compendium recommendations list the specific cancer stage, the treatment regimen and/or the line of therapy for bevacizumab (Avastin). UnitedHealthcare and Oxford will continue to reimburse for bevacizumab for conditions with NCCN Categories of Evidence and Consensus of 1, 2A, and 2B as proven and we will extend our review to the cancer

stage, treatment regimen and/or line of therapy. If the administration of bevacizumab does not follow the NCCN Compendium specifics regarding treatment regimen and/or line of therapy, services will not be eligible for coverage and will be denied as unproven.

### **Implementation**

UnitedHealthcare and Oxford will implement a bevacizumab review process in the Fall 2010. Additional details regarding this process will be available in future additions of the Network Bulletin and on our physician portals.

### **Other entities**

At this time, the process for reviewing bevacizumab claims has not been changed for benefits issued or administered by AmeriChoice®, Evercare®, Neighborhood Health Plan, Mid Atlantic Health Plan, PacifiCare, the River Valley entities, and SecureHorizons®. Any changes will be announced in future issues of Network Bulletin and on our Web sites.

### **Oncology Coverage: Proton Beam Radiation Therapy Policy**

UnitedHealthcare and its affiliates have recently reviewed the clinical evidence regarding Proton Beam Radiation Therapy (PBT) and concluded that PBT is proven for the treatment of:

- arteriovenous malformations (AVMs) and
- melanoma of the uveal tract.

PBT is proven non-preferentially as one form of external beam radiation therapy for the treatment of:

- intracranial and skull base tumors
- prostate cancer

Clinical evidence supporting the use of PBT for the treatment of prostate and intracranial and skull base tumors is limited and conflicting. UnitedHealthcare will continue to review clinical evidence surrounding the use of PBT for the treatment of these cancers and may modify this conclusion at a later date based upon the evolution of the published clinical evidence.

Clinical studies have examined the use of PBT for treating other cancers. The literature review demonstrates inadequate clinical evidence of safety and/or efficacy in published, peer-reviewed medical literature. Therefore, UnitedHealthcare has determined there is insufficient data to conclude that PBT is safe or effective for treating the cancers not listed above; coverage requests for treating these cancers will be denied as unproven.

The PBT policy is available for your review at *UnitedHealthcareOnline.com > Tools & Resources > Policies, Protocols, Administrative Guides > Medical Policies > Proton Beam Radiation Therapy.*

### **Implementation**

UnitedHealthcare will implement a post service claim review for PBT services rendered on or after September 1, 2010. Additional details regarding this process will be available in future additions of the Network Bulletin and on our physician portal.

### **Other entities**

At this time, the process for PBT claims for benefits issued or administered by AmeriChoice, Evercare, Neighborhood Health Plan, Mid Atlantic Health Plan, PacifiCare, UnitedHealthcare of River Valley Inc, and SecureHorizons® have not been changed. Any changes will be announced in future issues of Network Bulletin and on our Web site(s).

### **EDUCATIONAL OPPORTUNITY:**

#### **20th Annual Mayo Clinic Hematology/Oncology Reviews**

**Thursday July 29th – Saturday July 31st, 2010**

The Ritz-Carlton Amelia Island, Amelia Island, Florida

Get Updated and Connected

**11th Annual Fellows' Research Presentations**

**Register online:** [www.mayo.edu/cme/hematology-oncology/index.html](http://www.mayo.edu/cme/hematology-oncology/index.html)

**CORPORATE MEMBERSHIP/SPONSORSHIP: (January 1 – December 31, 2010)**

FLASCO Members extend a big thanks to all of our 2010 Corporate Members/Sponsors (Companies listed below have either paid 2010 dues or have submitted letters of intent)

<b><u>DIAMOND</u></b>	<b><u>PLATINUM</u></b>	<b><u>GOLD</u></b>	<b><u>SILVER</u></b>	<b><u>BRONZE</u></b>
Celgene	Abraxis	Allos Therapeutics	Genzyme	Alexion Pharmaceuticals
Cephalon	AMGEN	Bristol Myers Squibb	Meda Pharmaceutical	Biogen Idec
Eli Lilly	AstraZeneca	Genomic Health		The France Foundation
Genentech	Bayer Onyx	Millennium Pharmaceuticals		
Novartis	Eisai, Inc.	US Oncology		
Sanofi-Aventis	GlaxoSmithKline	OSI Pharmaceutical		
	Oncology Supply/ION			
	Pfizer			
	Ortho Biotech			

**FLASCO MEETINGS:**

**October 2, 2010** – FLASCO Business of Oncology Summit – Tampa

**November 5-6, 2010** – FLASCO Fall Meeting – Miami

**April 15-16, 2011** – FLASCO Annual Meeting & Spring Session - Tampa

**OTHER MEETINGS/WEBCASTS**

**October 7-10, 2010** The Association of Physician Assistants in Oncology (APAO), 13<sup>th</sup> Annual APAO Conference, The Ritz Carlton – Amelia Island, Florida **For more information, please visit [www.focus-ed.net/apao](http://www.focus-ed.net/apao)**

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